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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,767	09/23/2003	Steven Gutteridge	BB1533USNA	4390

23906 7590 04/26/2006

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EXAMINER	
LI, RUIXIANG	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/668,767	GUTTERIDGE ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *10-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-9* is/are rejected.

7)☒ Claim(s) *6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09/23/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/20/04 & 1/26/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence alignment*.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group V, claims 1-9, drawn to an isolated nucleotide fragment comprising a nucleic acid sequence encoding an amino acid sequence identity of at least 80% when compared to the polypeptide set forth in SEQ ID NO: 128 in the reply filed on 03/28/2006 is acknowledged.
2. Claims 1-33 are pending. Claims 1-9 are under consideration. All other claims are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Information Disclosure Statement

3. The Information Disclosure Statements submitted on 02/20/2004 and 01/26/2005 have been received by the Office and the listed references have been considered by the Examiner.

Drawings

4. The drawings submitted on 09/23/2003 are accepted.

Claim Rejections—35 USC § 112, 1st paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-5 and 7-9 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising (a) a nucleic acid sequence encoding a ryanodine receptor having an amino acid sequence that is at least 80% identical to the polypeptide of SEQ ID NO: 128, does not reasonably provide enablement for an isolated nucleic acid comprising the complement of (a). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claims 1-5 are drawn to an isolated nucleic acid comprising: (a) a nucleic acid sequence encoding a ryanodine receptor having an amino acid sequence that is at least 80% identical to the polypeptide of SEQ ID NO: 128 or (b) the complement of (a); claims 7-9 are drawn to a recombinant construct and a host cell comprising the nucleic acid. It is noted that claim 1, part (b), neither requires the complement of (a) is a full complement of (a) of claim 1 (i.e., over its entire length) nor recites a functional

limitation for an nucleic acid comprising the complement. Thus, the claims are broad and encompass a genus of nucleic acids comprising the complement of claim 1, (a).

The prior art teaches an isolated DNA sequence that encodes a ryanodine receptor that shares a high degree of homology with the amino acid sequence of SEQ ID NO: 128 of the present invention (Takeshima et al., FEBS Letters 337:81-87, 1994; see attached sequence alignment). The prior art also teaches an isolated DNA sequence, which encodes a ryanodine receptor and shares 97.8% homology with nucleotides 1870 to 2735 of SEQ ID NO: 127 of the present invention (Puente et al., *Insect Biochemistry and Molecular Biology* 30:335-347, 2000; see attached sequence alignment). However, the prior art does not provide compensatory structural or correlative teachings regarding the huge genus of nucleic acids encompassed by the instant claims.

While providing sufficient directions and working examples on how to make and use an isolated nucleic acid comprising (a) a nucleic acid sequence encoding a ryanodine receptor having an amino acid sequence that is at least 80% identical to the polypeptide of SEQ ID NO: 128, the specification fails to provide sufficient guidance, directions or working examples on how to make and use an isolated nucleic acid comprising the complement of (a).

Since the claims do not require that the complement of (a) of claim 1 is a full complement of (a) of claim 1 (i.e., over its entire length) and do not recite a functional limitation for the nucleic acid comprising the complement, it would require undue experimentation to make and use the instantly claimed nucleic acids. Accordingly, the

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims.

Claim Rejections—35 USC §112, 2nd paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "wherein the amino acid sequence of the polypeptide" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections—35 USC § 102(b)

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-5 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Takeshima et al. (FEBS Letters 337:81-87, 1994).

Takeshima et al. teach a ryanodine receptor (Fig. 2) and its encoding DNA sequence (page 82). Since the ryanodine receptor of Takeshima et al. shares a high

degree of homology with the amino acid sequence of SEQ ID NO: 128 of the present invention (see attached sequence alignment), the complementary sequence of the DNA sequence of Takeshima et al. comprises the complement of (a) of claim 1. It is noted that claim 1, part (b), does not require the complement of (a) is a full complement of (a) of claim 1 (i.e., over its entire length). Takeshima et al. further teach a recombinant construct and a host cell comprising the DNA sequence (bottom of right column of page 81) and use of CHO cells as host cells (top of right column of page 81). Thus, the teachings of Takeshima et al. meet the limitations of claims 1-5 and 7-9.

11. Claims 1-5 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Puente et al. (*Insect Biochemistry and Molecular Biology* 30:335-347, 2000).

Puente et al. teach a ryanodine receptor (Fig. 3) and its encoding DNA sequence (left column of page 338 and Fig. 1). Since the DNA sequence of Puente et al. shares 97.8% homology with nucleotides 1870 to 2735 of SEQ ID NO: 127 of the present invention (see attached sequence alignment), the complementary sequence of the DNA sequence of Puente et al. comprises the complement of (a) of claim 1. It is noted that claim 1, part (b), does not require the complement of (a) is a full complement of (a) of claim 1 (i.e., over its entire length). Puente et al. further teach a recombinant construct and a host cell comprising the DNA sequence, including E. coli XL1 Blue and E. coli SURE (the 3rd and 4th paragraphs of left column of page 337; and section 3.1 at pages 338-339). Thus, the teachings of Puente et al. meet the limitations of claims 1-5 and 7-9.

Claim Objections—Minor Informalities

12. Claim 6 is objected to because it uses an indefinite article to refer to a unique sequence; "a nucleotide sequence of SEQ ID NO: 127" should be amended to "the nucleotide sequence of SEQ ID NO: 127".

It is also suggested that "an isolated nucleotide fragment" recited in the claims be amended to "an isolated nucleic acid". Appropriate correction is required.

Conclusions

13. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [Brenda.Brumback@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is

more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Ruixiang Li

RUIXIANG LI, PH.D.
PRIMARY EXAMINER

Ruixiang Li, Ph.D.
Primary Examiner
April 25, 2006